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CytoDyn Announces Publication of Peer-Reviewed Paper, “Suppression of Human and Simian Immunodeficiency Virus Replication with the CCR5-Specific Antibody Leronlimab in Two Species”

VANCOUVER, Washington, April 12, 2022 (GLOBE NEWSWIRE) -- CytoDyn Inc. (OTCQB: CYDY) (“CytoDyn” or the “Company”), a late-stage biotechnology company developing leronlimab, a CCR5 antagonist with the potential for multiple therapeutic indications, today announced the publication of a peer-reviewed research paper entitled “Suppression of human and simian immunodeficiency virus replication with the CCR5-specific antibody Leronlimab in two species” in the open-access journal PLOS Pathogens.

The study followed five HIV+ human participants who, after successfully transitioning to once weekly subcutaneous leronlimab, halted their previous daily oral antiretroviral therapy regimens. These five participants came from an extension study, consisting of patients who were virologically suppressed in a prior study of leronlimab. Of the ten patients enrolled in the extension study, four individuals experienced viral rebound and stopped leronlimab monotherapy, and one individual withdrew, leaving five long-term participants. All five long-term participants successfully maintained HIV suppression via leronlimab monotherapy for over seven years, with no evidence of viral escape. It is important to note that these five participants on leronlimab monotherapy exhibited a higher frequency (7.1%) of transient episodes of plasma viremia, termed viral blips, than those on combinational oral antiretroviral regimens (2.0%). To monitor the anatomical penetrance of leronlimab, rhesus macaques acutely infected with simian human immunodeficiency virus (SHIV) were treated with high intravenous doses of leronlimab for 12 weeks. Leronlimab treatment reduced SHIV viral loads by 10,000 fold and leronlimab was found within all anatomical compartments analyzed, including mucosal and lymphatic tissues, sites of early viral replication after transmission and latency, respectively.

Jonah Sacha, Ph.D., the lead study author, who is a CytoDyn scientific advisor and an Oregon Health & Science University professor, stated, “To our knowledge, these data represent the longest administration of monoclonal antibody monotherapy for HIV in people to date.”

About CytoDyn

CytoDyn is a clinical-stage biotechnology company focused on the development and commercialization of leronlimab, an investigational humanized IgG4 monoclonal antibody (mAb) that is designed to bind to C-C chemokine receptor type 5 (CCR5), a protein on the

surface of certain immune system cells that is believed to play a role in numerous disease processes. CytoDyn is studying leronlimab in multiple therapeutic areas, including infectious disease, cancer, and autoimmune conditions.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as "believes," "hopes," "intends," "estimates," "expects," "projects," "plans," "anticipates" and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Forward-looking statements specifically include statements about leronlimab, the Company's ability to resolve the clinical holds recently imposed by the FDA, leronlimab's safety and effectiveness, and the Company's ability to obtain regulatory approval for commercial sales. The Company's forward-looking statements are not guarantees of performance, and actual results could vary materially from those contained in or expressed by such statements due to risks and uncertainties including: (i) the regulatory determinations of leronlimab's safety and effectiveness to treat the diseases and conditions for which we are studying the product by the U.S. Food and Drug Administration (FDA) and various drug regulatory agencies in other countries; (ii) the Company's ability to raise additional capital to fund its operations; (iii) the Company's ability to meet its debt obligations; (iv) the Company's ability to recruit a permanent CEO and retain other key employees; (v) the Company's ability to enter into partnership or licensing arrangements with third-parties; (vi) the Company's ability to identify patients to enroll in its clinical trials in a timely fashion; (vii) the timely and sufficient development, through internal resources or third-party consultants, of analyses of the data generated from the Company's clinical trials required by the FDA or other regulatory agencies in connection with the Company's BLA resubmission for the HIV indication or other applications for approval of the Company's drug product; (viii) the Company's ability to achieve approval of a marketable product; (ix) the design, implementation and conduct of the Company's clinical trials; (x) the results of the Company's clinical trials, including the possibility of unfavorable clinical trial results; (xi) the market for, and marketability of, any product that is approved; (xii) the existence or development of vaccines, drugs, or other treatments that are viewed by medical professionals or patients as superior to the Company's products; (xiii) regulatory initiatives, compliance with governmental regulations and the regulatory approval process; (xiv) legal proceedings, investigations or inquiries affecting the Company or its products; (xv) general economic and business conditions; (xvi) changes in foreign, political, and social conditions; (xvii) stockholder actions or proposals with regard to the Company, its management, or its board of directors; and (xviii) various other matters, many of which are beyond the Company's control. The Company clinurges investors to consider specifically the various risk factors identified in its most recent Form 10-K, and any risk factors or cautionary statements included in subsequent Form 10-Qs and Form 8-Ks, filed with the Securities and Exchange Commission. Except as required by law, the Company does not undertake any responsibility to update any forward-looking statements to take into account events or circumstances that occur after the date of this press release.

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